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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,139	05/04/2001	Vincent Petiard	88265-4022	1875

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WASHINGTON, DC 20005-3502

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

13

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,139

Applicant(s)

PETIARD ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's supplemental preliminary amendment filed 12/23/2003 has been entered. Claims 1-5 and 7-8 are pending.

Claim Objections

1. Claim 7 is objected to because of the following informalities: the word "choroplastic" might be typographic error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the genetic material of cocoa from mitochondrial or chloroplastic DNA (See pg. 3, last paragraph), seed storage protein gene (See pg. 9, second paragraph) and chitinase gene (See pg. 10, second paragraph) via a DNA detection technique, does not reasonably provide enablement for determining any genetic material of cocoa in fermented or roasted beans via a DNA detection technique. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

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"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to a method for determining a genetic material of cocoa in fermented or roasted beans, chocolate or a food component containing cocoa via applying a DNA detection technique to the food component. The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims encompass any nucleic acid material of cocoa in fermented or roasted beans, or chocolate or a food component containing cocoa to be determined.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since determination of a use of any genetic material of cocoa in fermented or roasted beans for the many nucleic acid sequences would require, initially, studies to demonstrate some utility or use. This study is an inventive, unpredictable and difficult undertaking in itself. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

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The art in biotechnology, as relates to the association of any gene material of cocoa in fermented or roasted beans is highly unpredictable. For example, In Spencer et al. (US 5,668,007, issued September 16, 1997), Spencer et al. disclose flavor precursors in cocoa, which is identified, and that the genes coding for it is identified and sequenced (See the Abstract). Spencer et al. further disclose that the protein is produced by DNA recombinant techniques (See column 1, lines 61-67) and detectably labeled cDNA is prepared (See column 2, lines 45-53). Therefore, the work of Spencer et al. would have been used for determining the genetic material of cocoa in fermented or roasted beans, but Spencer et al. do not disclose determining any genetic material of cocoa in fermented or roasted cocoa bean.

Working Examples

The specification has a working example of using nucleic acid primer from rDNA 5S gene and from seed storage protein gene (See pg. 9, second paragraph) or chitinase gene (See pg. 10, second paragraph).

Guidance in the Specification.

The specification provides no guidance on determining any genetic material of cocoa in fermented or roasted beans, chocolate or a food component containing cocoa via applying any genetic material.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the level of unpredictability in the art is high (See Spencer et al.), the specification provides one with no written description or guidance that leads one to a reliable method of using any nucleic acids material of cocoa. One of skill in the art cannot readily anticipate the effect of determining the genetic material of cocoa in fermented or

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roasted beans, chocolate or a food component containing cocoa within the subject matter to which the claimed invention pertains. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of any working examples and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-5 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 4-5 and 7 are vague and indefinite because of the phrase “derived from”. It is unclear what are the metes and bounds of the genetic material of cocoa to be detected in fermented or roasted beans, chocolate or a food component containing cocoa.

b. Claims 1-5 and 7-8 are vague and indefinite because it is unclear how the method is done in terms of determining the genetic material of cocoa in fermented or roasted beans.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Spencer et al. (US 5,668,007, issued September 16, 1997).

Spencer et al. disclose flavor precursors in cocoa which is identified, and that the genes coding for it is identified and sequenced (See the Abstract). Spencer et al. further disclose that the protein is produced by DNA recombinant techniques (See column 1, lines 61-67) and detectably labeled cDNA is prepared (See column 2, lines 45-53). Therefore, the work of Spencer et al. would have been used for determining the genetic material of cocoa in fermented or roasted beans. Thus, the teachings of Spencer et al. anticipate the limitations of claims.

7. U.S. patent NO. 6297273 and DE 10019289 are made of record as references of interests since DE 100 19 289 A1 discloses a method for detecting cocoa components in cocoa products comprising amplification and identification of selected DNA fragments (See the Abstract).

Summary

8. No claims are allowable.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.


Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J.T

May 31, 2004


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

6/1/04